The Florida House of Representatives

Office of the Speaker

Dean Cannon
Speaker

For Immediate Release:
Tuesday, April 12, 2011

Contact:
Katie Betta, (850) 339-7087; Or
Lyndsey Cruley, (850) 487-8148

Comprehensive Strategy to Address Prescription Drug Abuse Unanimously Passes House Appropriations Committee

Tallahassee, Fla. – The House Appropriations Committee today unanimously passed CS/HB 7095. The legislation represents a comprehensive strategy to curtail prescription drug abuse in the State of Florida.

"People sent us to Tallahassee to work together to find solutions," said Florida House Speaker Dean Cannon (R-Winter Park). "This broad-based approach incorporates the hard work of Governor Scott, Attorney General Bondi, House Members and countless stakeholders who recognize the need to address this public health epidemic."

"This comprehensive strategy addresses the serious concerns of doctor-shopping, fraudulent prescriptions, and inappropriate behavior by dispensing physicians and pharmacies, it also empowers FDLE and local law enforcement to secure the remaining inventory of Schedule II and III controlled substances once the strategy is enacted," said Representative Robert Schenck (R-Spring Hill), chairman of the House Health & Human Services Committee.

"By cutting the problem off at the source, instituting strict registration and reporting requirements for physicians, distributors and pharmacies, and providing law enforcement the tools necessary to investigate and prosecute these crimes, we have crafted a front-end solution with the best chance of success," concluded Speaker Cannon.

House Bill 7095

Sets Strict Registration and Reporting Requirements for Practitioners Who Prescribe Controlled Substances to Treat Chronic Pain

- Require registration for practitioners prescribing controlled substances to treat chronic, non-cancer pain.
- Require prescribers of controlled substances to maintain a log of all prescriptions.
- Require prescribers to make logs available to the Department of Health (DOH) and the Florida Department of Law Enforcement (FDLE) upon demand.
- Require tamper proof prescription pads purchased from an approved vendor.
- Limit the supply of approved prescription pads and require vendors to report practitioner purchases of prescription pads.
- Enact standards of care for all physicians prescribing controlled substances for treatment of chronic non-cancer pain.
- Require initial risk assessment and ongoing monitoring.
- Provide for exceptions for credentialed interventional pain physicians.

Bans Physician Dispensing of Schedules II and III

- Ban physician dispensing of controlled substances in Schedules II and III.
- Provide criminal penalties and grounds for disciplinary action against a physician or osteopathic physician.
- The ban does not prohibit direct administration of medications.

Includes Reporting and Credentialing Requirements and Distribution Limits for Distributors of Controlled Substances

- Buy back controlled substances within the authorized period from practitioners no longer permitted to dispense.
- Report distributions of controlled substances listed in Schedules II, III, IV, and V in Florida.
- Specific information must be included in the reports.
- Credential physicians and pharmacies that purchase Schedule II or Schedule III controlled substances.
- Credentialing policies must be submitted to DOH as part of an application for a permit or to renew a permit for a prescription drug wholesale distributor.
- Credentialing must include:
    - Determination of the clinical nature of the entity;
    - Review of the receiving entity's history of purchasing Schedule II and Schedule III controlled substances;
    - Determination that purchasing history, if any, is consistent with and reasonable for that entity's clinical business needs; and
    - Level 2 background screening of any person who owns, manages, oversees or controls the operation of the purchasing entity, including officers and members of the board of directors of an entity that is a corporation (with exceptions for large corporations).

- Prohibition against distributing more than 5,000 unit doses of specific drugs (oxycodone, hydromorphone, hydrocodone, or methadone or their derivatives) to a retail pharmacy (a pharmacy serving the general public) in any given month.
- Requirement for distributers to investigate suspicious transactions, including those involving more than 5,000 unit doses of controlled substances in any given month.
- Grounds for disciplinary action including loss of distributing permit for failure to exercise due diligence.

Requires Reporting and Dispensing Requirements for Pharmacies

- Strengthening pharmacy permitting process:
    - Mandatory on-site inspections
    - Disclosure of financial interests
    - Requirement to have a designated pharmacy manager responsible for compliance
    - Specific grounds for denial of permits including criminal history, prior non-compliance with specific regulations.
- Community pharmacies may not dispense a controlled substance listed in Schedule II or Schedule III unless the pharmacy:
    - Is wholly owned by a corporation whose shares are publicly traded on a recognized stock exchange; or
    - Is wholly owned by a corporation having more than $100 million of annual business revenues in this state; or
    - Has been continuously permitted for at least 10 years; or,
    - Is wholly owned or operated by a licensed hospice, hospital or nursing home or exclusively serves hospice, hospital or nursing home patients; or
    - Is majority owned by one or more licensed pharmacists; or
    - Received or renewed a permit after January 1, 2012, such that it is subject to the new permitting requirements.
- Require pharmacies dispensing controlled substances to maintain a log of all prescriptions filled.
- Require pharmacy to make the controlled substances log available to DOH or FDLE upon request.

Increases the Department of Health's Monitoring Responsibility

- Must actively monitor purchasing from wholesalers to identify patterns that are inconsistent with the purchasing entity's clinical needs.
- Must actively monitor practitioner purchases of approved prescription pads.
- Must report suspicious purchases to FDLE for coordination with local law enforcement.
- Must declare a public health emergency regarding controlled substance prescription drugs in order to authorize specific actions for high risk practitioners immediately after the bill becomes law.

Outlines Coordination and Monitoring Expectations and Increases Investigative Authority of Law Enforcement

- Must investigate purchases that are inconsistent with the entity's clinical needs.

- The Attorney General and FDLE shall coordinate with federal law enforcement agencies to accomplish the provisions of the act.
- Must quarantine Schedule II and Schedule III controlled substances possessed by high-risk practitioners and provide security as necessary to protect the public health immediately after the bill becomes law.
- Authority to inspect records of prescribers and dispensers of controlled substances.
- Monitoring and reporting of investigations and prosecutions to determine the most effective interventions.

Specifies Criminal Penalties Related to Unlawful Dispensing, Theft of And Failure to Report the Loss of Controlled Substances

- 3rd degree felony for practitioner dispensing of Schedules II and III.
- 1st degree misdemeanor for pharmacy employees failure to report attempt to fraudulently obtain controlled substances.
- 2nd degree felony for burglary with intent to obtain controlled substances.
- 3rd degree felony for theft of controlled substances.
- 2nd degree misdemeanor for failure to report loss of Schedules III, IV, or V controlled substances.
- 1st degree misdemeanor for failure to report Schedule II controlled substance.
- 3rd degree felony for knowingly submitting a false drug distribution report.
- 3rd degree felony for distributing controlled substances improperly.

Maintains Registration and Regulation of Pain Clinics

- Maintain requirement for registration of pain clinics
- Enact specific provisions of the clinic regulations into law. All clinic standards except:
    - Risk management program
    - Patient drug testing, due to risk assessment and ongoing monitoring for all physicians treating chronic pain with controlled substances, regardless of setting.
    - Script limits, due to ongoing monitoring of use of prescription pads
- Sunset the pain clinic regulations in 2016.

Modifies Implementation of the Prescription Drug Monitoring Program

- Prohibit donations of pharmaceutical manufacturers from being used to support the monitoring program.
- Modify data submission requirement to seven days (from 15 days).
- Revise direct support organization provisions to establish DOH as responsible agency in place of the Office of Drug Control

Sets Specific Appropriation to Aid Law Enforcement Activities

- An appropriation of $3 million in non-recurring funds is provided to defray the cost to FDLE and local law enforcement agencies of securing Schedule II and Schedule III controlled substance inventories during the quarantine period, investigative activities, and prosecution of crimes related to prescribed controlled substances.

# # #